Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* WENDY A. BAHNSEN *et al.*, *Plaintiffs*, v. BOSTON SCEINTIFIC NEUORMODULATION CORPORATION, *Defendant.*	Civil Action No. 11-1210 **OPINION**

John Michael Vazquez, U.S.D.J.

This matter is a False Claims Act case regarding medical supplies billed to Medicare. Currently pending before the Court is a motion for summary judgment filed by Defendant Boston Scientific Neuromodulation Corporation ("BSNC" or "Defendant"). D.E. 299. Plaintiffs Wendy Bahnsen and Carolina Fuentes (collectively "Plaintiffs" or "Relators") filed a brief in opposition, D.E. 313, to which Defendant replied. D.E. 333. Plaintiff, after receiving the Court's leave, filed a sur-reply brief. D.E. 341.[1] The Court reviewed the submissions made in support and in opposition of the motion and considered the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons that follow, Defendant's motion for summary judgment is **DENIED**.

[1] In this Opinion, Defendant's motion for summary judgment (D.E. 299) will be referred to as "Def. MSJ." Plaintiffs' brief in opposition (D.E. 313) will be referred to as "Pl. Opp." Defendant's reply brief (D.E. 333) will be referred to as "Def. Rep." Plaintiffs' sur-reply brief (D.E. 341) will be referred to as "Pl. S. Rep.".

I. FACTS AND PROCEDURAL HISTORY

A. Factual Background

Defendant BSNC is a wholly-owned subsidiary of Boston Scientific Corporation. Plaintiffs' Amended Complaint ("Am. Compl.") ¶ 16; D.E. 19. During the relevant time period, BSNC "marketed, sold, supplied and submitted claims for . . . the Precision Plus^{TM} SCS System." *Id.* As a government supplier of medical equipment, BSNC was responsible for responding to requests to replace external equipment. Its Billing and Collections Department was responsible for processing the necessary documentation. *Id.* ¶ 27.

BSNC's Precision Plus Spinal Cord Stimulation ("SCS") is an implantable spinal cord stimulator. Defendant's Statement of Material Facts Not In Dispute ("DSOMF") ¶ 1; D.E. 299-2.[2] SCS has been used as a treatment method for chronic back pain. *Id.* ¶ 4. During an outpatient procedure,[3] a physician threads leads that contain electrodes into the epidural space above the patient's spinal canal. The leads can then be connected to a power supply to receive pulses of electric current. *Id.* ¶ 6. Physicians implant a rechargeable power source, an implantable pulse generator ("IPG"), to the leads. *Id.* ¶ 11. Patients may also purchase supplies from BSNC to use with the SCS, including a charger, patient remote control, a charging belt, and disposable adhesive patches (collectively, the "Replacement Supplies").[4] *Id.* ¶ 13. BSNC

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[2] The Opinion cites to Defendant's Statement of Material Facts Not In Dispute unless the parties disagree about the fact(s) or supplemental information is necessary.

[3] Medicare requires specific coverage criteria to be met before it will cover the implantation of a SCS. DSOMF ¶ 18. One such criteria is that a physician prescribe, or order, that a SCS be implanted. *Id.* ¶¶ 20, 22. When the coverage criteria are met, Medicare will reimburse both the hospitals and physicians for the costs of the SCS implant procedure, a SCS, and the initial set of external accessories. *Id.* ¶ 25. The initial implantation procedure is not at issue in this case.

[4] The Replacement Supplies can also include a remote control holster, a charger base station, and power cords. The listed external accessories and supplies are first provided to the patient at the time of the initial implantation of the SCS. These items are not at issue in the current case.

alleges that its "FDA-approved Patient System Handbook recommends that patients use the adhesive patches over the charging belt, because the patches maintain better alignment between the charger and the IPG." *Id.* ¶ 15. The external supplies, mainly the adhesive patches, for the SCS are at the heart of Plaintiffs' allegations.

Plaintiffs "are medical billers and former BSNC employees who worked in the [B]illing and [C]ollections [D]epartment." Pl. Opp. at 10; D.E. 313. BSNC employed Plaintiff Wendy Bahnsen from March 31, 2008 to October 15, 2009. Am. Compl. ¶ 7. Ms. Bahnsen first worked in the BSNC Customer Service Department before being transferred in 2009 to BSNC's Billing and Collections Department. *Id.* ¶ 8. In the Billing and Collections Department, Ms. Bahnsen worked as a Reimbursement and Claims Management Specialist. "Her primary task was to submit claims for payment to Medicare, Medicaid and private insurance companies to obtain payment for BSNC's external medical equipment associated with BSNC's spinal cord stimulation medical devices." *Id.* ¶ 9. BSNC terminated Ms. Bahnsen's employment in October 2009. *Id.* ¶ 7.

Plaintiff Carolina Fuentes worked for BSNC from May 2005 to June 2010. *Id.* ¶ 13. Ms. Bahnsen first worked as the Administrative Assistant to BSNC's Vice President of Health Economics and Reimbursement before being transferred in 2009 to BSNC's Billing and Collections Department. BSNC terminated Ms. Fuentes' employment in October 2009. *Id.*.

During the course of their employment in BSNC's Billing and Collections Department, both Plaintiffs submitted claims to Medicare seeking reimbursement for the Replacement Supplies associated with the SCS. Def. MSJ. at 17. Plaintiffs assert that through this work, they

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Instead, this case concerns the replacement of those items once the initial supply is exhausted or in need of replacement.

became aware that BSNC was knowingly submitting thousands of false claims for the external supplies to Medicare for reimbursement. Pl. Opp. at 10. Plaintiffs claim, among other things, that Defendant submitted claims for the replacement supplies without written physician orders and/or with fabricated diagnosis codes. Plaintiffs do not allege that beneficiaries did not receive the replacement supplies or that Defendant billed for supplies that it never provided.

The replacement supplies associated with the SCS are submitted to A/B Medicare Administrative Contractors ("MACs")[5] for reimbursement. *Id.* ¶ 27. These supplies fall under the supplies category of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). *Id.* ¶ 31. Plaintiffs' Response to Defendant's Statement of Undisputed Material Facts ("Pl. R. DSOMF") ¶ 1; D.E. 313-1. Between 2006 and 2010, BSNC submitted claims for supplies associated with the SCS to A/B MACs for payment. DSOMF ¶ 32.

Relators allege that BSNC submitted at least 6,058 claims for SCS supplies.[6] Pl. R. DSOMF ¶ 33. They further assert that 6,047 of those claims were false because BSNC "fail[ed] to obtain valid physician orders before submitting a claim to the Government . . . fabricated diagnosis codes, fabricated referring providers, falsely certified compliance with Medicare rules and regulations, and falsely certified that the supplies for which they sought reimbursement were medically indicated and necessary." *Id.* ¶ 34. BSNC responds that 4,594 of the 6,047 allegedly

[5]MACs are private health insurance carriers that contract with the Centers for Medicare and Medicaid Services ("CMS"). MACs act as the primary operational contact between the Medicare program and health care providers.

[6] Defendant and Plaintiffs disagree over the number of claims at issue. Defendants argue that certain submissions to the A/B MACs were not claims because they were not processable or they were reminders, resubmitted, or adjusted submissions of claims. Plaintiffs argue that these submissions are claims. *See* DSOMF ¶¶ 72, 74, 75-76; Pl. R. DSOMF ¶¶ 72, 74, 75-76.

false claims were for boxes of the SCS adhesive patches.[7] DSOMF ¶ 35. The parties agree that BSNC received, at most, approximately $470,379 in Medicare reimbursement for the alleged false claims at issue. DSOMF ¶ 39; Pl. R. DSOMF ¶ 39.

As noted, BSNC terminated Plaintiff Bahnsen's employment on October 15, 2009 and Plaintiff Fuentes' employment in June 2010. DSOMF ¶ 40. After terminating Plaintiff Bahnsen's employment, BSNC, in conjunction with legal counsel, reviewed its billing practices. *Id.* ¶ 41. At some point during this review BSNC alleges that it decided to send a letter to Palmetto GBA, the A/B MAC responsible for processing the relevant Medicare claims. BSNC claims to have done so on December 7, 2009. DSOMF ¶ 42; Def. MSJ, D.E. 299-16 ("Palmetto letter"). Plaintiffs contest whether Defendant ever sent the Palmetto letter. Pl. R. DSOMF ¶ 47. BSNC has not produced evidence demonstrating that Palmetto received the letter.

The Palmetto letter explains that "[w]e[, BSNC,] wish to bring to your attention, and seek confirmation from you that Palmetto is aware of and agrees with, the process Boston Scientific Neuromodulation Corporation ("the Company") uses to submit claims for Medicare reimbursement for certain of its external ancillary replacement products." Palmetto Letter. The "external ancillary replacement products" referenced are the replacement supplies at issue. Specifically, the letter provides that:

> When billing for Ancillary Products, it is not always viable to communicate with the treating physician regarding the patient's diagnostic code in a timeframe that meets the patient's needs. . . . Accordingly, when no code is available directly from the physician, the Company's billing department has placed a generic diagnostic code, particularly ICD 724.1 or 724.2, on the claim form reflecting the types of indication for which the SCS System is ordinarily

[7] Defendant also asserts that Plaintiffs "conceded that for at least 3,201 of the 6,027 claims, BSNC actually did obtain a separate physician order for replacement external accessories before billing the Government." DSOMF ¶ 37. Plaintiffs dispute this. Pl. R. DSMOF ¶ 37.

> implanted. . . . Unlike the implant itself, there are no particular coverage requirements for these Ancillary Products . . . to the Company's knowledge, there is no certificate of medical necessity requirement for any of these items.

Def. MSJ.;D.E. 299-16.

Palmetto never responded to the letter. BSNC asserts that "[a]fter giving Palmetto a reasonable time to object to the statements in the letter, BSNC decided to resubmit 1,194 claims to Palmetto, which had previously been denied, using its existing billing policies." DSOMF ¶ 48. BSNC further alleges that after these resubmissions, Palmetto paid BSNC approximately $166,457 for 377 of the 1,194 resubmitted claims. *Id.* ¶ 49.

B. Procedural Background

On March 2, 2011, Plaintiffs filed their *qui tam* Complaint alleging that BSNC submitted false claims to the Government in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et. seq.* D.E. 1. As required by the FCA, Plaintiffs Complaint was filed under seal and the Government was given an opportunity to review the allegations. D.E. 1. Ultimately, the Government decided to not intervene in this case. D.E. 8. The Complaint was unsealed and served on Defendant. D.E. 9. Plaintiffs then filed an Amended Complaint in September 2012. D.E. 19. In response, Defendant filed motions to strike, to dismiss, and to disqualify Plaintiffs' counsel. D.E. 28-30. Judge Wigenton denied all three of Defendant's motions. D.E. 49.

On June 28, 2013, Defendant filed an Answer to the Amended Complaint and raised counterclaims against Plaintiffs.[8] D.E. 54. Defendant, thereafter, amended its counterclaims against Plaintiffs. D.E. 84. In response, Plaintiffs moved to dismiss the amended counterclaims. D.E. 85. Judge Wigenton denied Plaintiffs' motion. D.E. 132. Plaintiffs have since moved for

[8] Plaintiffs have also moved for summary judgment as to the counterclaims. The Court addresses the motion in a separate opinion.

summary judgment on the amended counterclaims, D.E. 296, which the Court is addressing in a separate opinion.

On December 22, 2014 the case was reassigned from Judge Wigenton to Judge Arleo. D.E. 149. Then, on March 1, 2016, the case was again reassigned from Judge Arleo to the undersigned. D.E. 226. The Court then granted the parties' stipulated voluntary partial dismissal. D.E. 293. In January 2017, Defendant filed the current motion.

The motion pertains to Counts I and II of the Amended Complaint, both of which charge violations of the FCA. D.E. 19 ¶¶ 164-77. Plaintiffs allege that Defendant submitted claims that contained diagnosis codes that were different than those provided by the treating physicians or which were "made up" by Defendant. *Id.* ¶¶ 32-35, 38, 39. Plaintiffs further assert that Defendant submitted claims before having a written physician order on file. *Id.* ¶ 41.

II. SUMMARY JUDGMENT STANDARD

A moving party is entitled to summary judgment where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact in dispute is material when it "might affect the outcome of the suit under the governing law" and is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over irrelevant or unnecessary facts will not preclude granting a motion for summary judgment. *Id.* "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the nonmoving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255)). A court's role in deciding a motion for summary judgment is not to evaluate the

evidence and decide the truth of the matter but rather "to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249.

A party moving for summary judgment has the initial burden of showing the basis for its motion and must demonstrate that there is an absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). After the moving party adequately supports its motion, the burden shifts to the nonmoving party to "go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal quotation marks omitted). To withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict the moving party. *Anderson*, 477 U.S. at 250. "[I]f the non-movant's evidence is merely 'colorable' or is 'not significantly probative,' the court may grant summary judgment." *Messa v. Omaha Prop. & Cas. Ins. Co.*, 122 F. Supp. 2d 523, 528 (D.N.J. 2000) (quoting *Anderson*, 477 U.S. at 249-50)).

Ultimately, there is "no genuine issue as to any material fact" if a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case." *Celotex Corp.*, 477 U.S. at 322. "If reasonable minds could differ as to the import of the evidence," however, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 250-51.

III. ANALYSIS[9]

As noted, the FCA is found at 31 U.S.C. § 3729 *et seq*. "The False Claims Act was adopted in 1863 and signed into law by President Abraham Lincoln in order to combat rampant fraud in Civil War defense contracts." *United States ex rel. Spay v. CVS Caremark Corp.*, No.

[9] The Court has jurisdiction to hear this motion under 31 U.S.C. § 3729(a) and 28 U.S.C. § 1331.

15-3548, 2017 WL 5491935, at *4 (3d Cir. Nov. 16, 2017) (quoting *Kellogg Brown & Root Sers., Inc. v. U.S., ex rel. Carter*, 135 S.Ct. 1970, 1973 (2015)). Since that time, the FCA has evolved but continues to penalize persons who knowingly submit fraudulent claims to the Government. *See U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1152 (3d Cir. 1991). The FCA's primary purpose "is to indemnify the government - through its restitutionary penalty provisions – against losses caused by a defendant's fraud." *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001) (citing *United States ex rel Marcus v. Hess*, 317 U.S. 537, 549, 551052 (1943)).

A private party, called a relator, may bring a *qui tam*[10] action on behalf of the Government alleging a violation of the FCA. 31 U.S.C. § 3730(b). The "FCA's *qui tam* provision allows individuals to bring claims on behalf of the government, and rewards successful plaintiffs with potentially very substantial recoveries." *CVS Caremark Corp.*, 2017 WL 5491935, at *5. In its current form, the FCA "imposes civil penalties and treble damages on defendants who submit false or fraudulent claims to the government. Individual relators can receive between 15% and 30%" of the recovered amount. *Id.*

Section 3729(a)(1) creates liability for "any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[11] To establish "a prima facie violation of the FCA, a Plaintiff-Relator 'must

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[10] The term *qui tam* action comes from the Latin phrase, *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning "who as well for the king as for himself sues in this matter." Black's Law Dictionary (10th ed. 2014). A *qui tam* action is an "action brought under a statute that allows a private person to sue for a penalty, part of which the government or some specified public institution will receive." *Id.*

[11] In May 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), "which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. §

prove that (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" *Druding v. Care Alternatives, Inc.*, 164 F. Supp. 3d 621, 627 (D.N.J. 2016) (citing *Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)). Ultimately, a FCA claim includes four elements: "falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citation omitted).

The definitions of claim, materiality, and knowing are all statutorily defined. "[C]laim means any request or demand . . . for money or property" that is presented to an "officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2). "[M]aterial means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4). "Knowing" or "knowingly," in turn, means "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information[.]" *Id.* at § 3729(b)(1). The scienter requirement, that is acting knowing or knowingly, does not mandate an intent to defraud but an innocent mistake or simple negligence is also insufficient. *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007) (citations omitted).The FCA does not, however, define false or fraudulent. The Third Circuit has found that in the context of a FCA case, "[a] statement is 'false' when it is

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3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B)." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 303 (3d Cir. 2011). The effective date of the FERA amendments was made retroactive to any claims pending as of June 7, 2008. *Id.* at 303-04. Here, Plaintiffs make allegations as to claims made both before and after June 7, 2008. The parties, however, only analyze the case in light of the FERA amendments, although Count I and Count II of the Amended Complaint refer to both the pre and post-FERA FCA provisions. The Court does not see a reason why the FCA, as it existed pre-FERA, would change its analysis.

objectively untrue." *U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014). While this case law offers guidance, there is no definitive test or definition for courts to apply when assessing what is objectively untrue in civil FCA cases.[12] Several courts have found that "errors based simply on faulty calculations or flawed reasoning are not false under the FCA." *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (citing *Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992)). Likewise, "imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA." *City of Green Bay*, 168 F.3d at 1018 (citing *Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1477–78 (9th Cir. 1996)). The Third Circuit has further held that the terms "false" and "fraudulent" have different meanings:

> A common definition of "fraud" is an intentional misrepresentation, concealment, or nondisclosure for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right." "False" can mean "not true," "deceitful," or "tending to mislead." The juxtaposition of the word "false" with the word "fraudulent," plus the meanings of the words comprising the phrase "false claim," suggest an improper claim is aimed at extracting money the government otherwise would not have paid.

U.S. ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 438 (3d Cir. 2004) (citing *Mikes v. Straus,* 274 F.3d 687, 695 (2nd Cir. 2001)).

Here the FCA claims concern the Medicare program, "which reimburses the health care costs incurred by program beneficiaries." *Omnicare Inc* ., 382 F.3d at 486-487. Medicare is

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[12] Marc Van Allen, *What is "False" under the False Claims Act?*, NAVIGATING THE GOVERNMENT CONTRACTS PROCESS (DECEMBER 5, 2017 3:04 P.M.), https://jenner.com/system/assets/assets/7917/original/2010_20WL_203650148_20Aspatore.pdf (noting that "the civil falsity standard has been articulated in many different ways and often in an *ad hoc* manner based on the particular facts of the case. In addition, with the civil falsity standard, courts often seem to focus more on *scienter* than falsity.").

administered by the Centers for Medicare and Medical Services ("CMS"), which is part of the Department of Health and Human Services ("HHS"). False claims under the FCA fall into two categories: factually false claims and legally false claims. *Wilkins*, 659 F.3d at 305 (citation omitted). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government[.]"[13] *Id.* By comparison, "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statue or regulation the compliance with which is a condition for Government payment." *Id.*

Legally false claims are further divided into two types: express and implied certifications. *Id.* An express false certification occurs when an entity certifies that it is in compliance with the legal requirements that are "prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* (citation omitted). Implied false certification liability arises when an entity makes a claim to the Government for payment while implying, but not expressly certifying, that it is in compliance with the legal preconditions for payment. *Id.* (citing *Mikes*, 274 F.3d at 699). In *Wilkins*, decided in 2011, the Third Circuit held that the implied false certification theory is viable under the FCA. *Id.* at 306. Yet, the Circuit cautioned that theory "should not be applied expansively[.]" *Id.* at 307. Instead, the *Wilkins* court indicated that the implied certification theory should be applied only to regulations that are preconditions of payment. *Id.* As a result, in the case before it, *Wilkins* court found that the implied certification theory did not apply because the relevant regulations concerned conditions

[13] In this case, the goods were not provided to the Government; instead, Defendants provided the replacement supplies to the Medicare beneficiaries. As a result, Defendant's claim would be factually false if, for example, it billed Medicare for replacement supplies that it never actually provided to the beneficiaries.

of program participation (and included an administrative mechanism to correct perceived deficiencies) rather than conditions of payment. *Id.* at 308-11.

The Supreme Court of the United States recently addressed FCA liability in *Universal Health Servs., Inc. v. United States ex rel Escobar*, 136 S. Ct. 1989 (2016). The Court held that the "implied false certification theory" can be a basis for FCA liability under certain circumstances. 136 S. Ct. at 1999, 2001. At least two conditions, according to the Supreme Court, had to be met before the theory could support FCA liability: the claim had to make "specific representations about the goods or services provided," and the "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements make those representations misleading half-truths." *Id.* at 2001.

The Court in *Escobar* further ruled that a defendant may be liable under the FCA even when what it failed to disclose information that was not designated by the Government as an express condition of payment. *Id.* at 2001 (finding that "[w]hether a provision is labeled as a condition of payment is relevant to but not dispositive of the materiality requirement"). The Supreme Court reasoned that if an express condition was required, then the Government may respond by "designating every legal requirement an express condition of payment." *Id.* at 2002. Instead, the *Escobar* Court found, the materiality requirement must be met as set forth in the FCA. *Id.* The Court added that the materiality requirement is "demanding" such that minor or insubstantial compliance does not qualify nor does merely showing that the Government "would have had the option to decline to pay if it knew of the defendant's noncompliance." *Id.* at 2003. The Court in *Escobar* also discussed the FCA's scienter requirement, noting that a claimant can have actual knowledge that a condition is material even if the Government did not designate it as a condition of payment. *Id.* at 2001. In support, the Supreme Court used the example of a

contract for guns, which did not expressly specify that the firearms had to actually shoot, but the claimant nevertheless knew that the Government regularly rescinds the contract if the guns do not fire. *Id.*

In this case, Defendant makes numerous arguments in support of its motion. BSNC argues that (1) it was not required to obtain a detailed physician order before submitting claims, (2) the allegedly fabricated diagnosis codes did not violate the False Claims Act , (3) it did not knowingly submit false claims because it informed Palmetto, the A/B MAC, about its billing practices, (4) Relators improperly inflated claim lines to increase damages, (5) Relators' claimed penalties are unconstitutionally excessive, and (6) Relators will not be able to identify which claims are purportedly false. On these bases, BSNC claims that it is entitled to summary judgment dismissing Counts I and II of the Amended Complaint. Def. MSJ. at 1. In the alternative, Defendant argues that it is entitled to partial summary judgment on the specific number of allegedly false claims at issue and the maximum civil penalty that could be imposed. The Court will address each argument in turn.

A. Written Physician Orders

Plaintiffs assert that a number of claims submitted by Defendant violated the FCA because BSNC did not have written physician orders for the replacement supplies before submitting the claims. The Amended Complaint appears to assert an express false certification theory as to the detailed physician orders. For example, the Amended Complaint indicates that when Defendant signed the claim form, it attested that the stated supplies were "medically indicated and necessary for the health of the patient[.]" Am. Compl. ¶ 42. Plaintiffs claim that the attestation was false because the physician orders were required to meet a finding of medically indicated and necessary as to the replacement supplies.

Defendant argues that it is entitled to summary judgment as to Plaintiffs' assertion that BSNC was required to obtain a detailed physician order before submitting claims for replacement supplies. Plaintiffs' allege that BSNC violated the FCA by knowingly "submitting claims to Medicare that falsely certified compliance with the 'detailed physician order' requirements contained in Chapter Five of the Medicare Program Integrity Manual." Def. Rep. at 3. Plaintiffs further allege that Chapter Twenty of the Medicare Claims Processing Manuel ("MCPM") "debunks [BSNC's] own argument that the physician order rules in Chapter 5 do not apply to DME claims submitted to A/B MACs." Pl. Opp. at 23. Defendant responds that Chapter Five of the Medicare Program Integrity Manuel ("PIM") [14] either does not apply, or does not unambiguously apply, to the claims at issue. Def. Rep. at 3.

As a threshold matter, the Court does *not* consider the 2016 version of the MCPM or the 2011 and 2016 versions of the PIM that Plaintiffs cite. Pl. Opp. at 23-25. These versions were promulgated after the conduct in question. The Court, therefore, reviews only the 2004 PIM that was in effect during the relevant timeframe. The Court finds, as is discussed below, that the requirements in the PIM are arguably ambiguous.

As an alternate argument, BSNC argues that Chapter Five of the PIM is vague as to whether it required a written order from a physician. Thus, BSNC continues, it did not act with

[14] The PIM and the MCPM are published documents, through which the CMS communicates "program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives." *See* CENTERS FOR MEDICARE & MEDICAID SERVICES, *Manuals*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html (last visited December 4, 2017). *See, e.g., Balko & Assocs. v. Sec., of U.S. Dept. of Health & Human Servs.*, 555 Fed. Appx. 188, 190 (3d Cir. 2014) (observing that an auditor of a Medicare provider "followed the procedures laid out in PIM).

the requisite knowledge.[15] Plaintiffs reply that the argument is an after-the-fact creation of Defendant's litigation counsel because Defendant believed that it was subject to the physician order requirement *at the time* it was submitting the relevant claims. The Court agrees with Plaintiff insofar as there are genuine issues of material fact as to whether Defendant believed, at the time that the claims were actually being submitted, that it needed a detailed physician order.

Generally, a defendant can defeat the FCA's scienter (or knowing) requirement if its acts in accordance with a good faith and objectively reasonable interpretation of an ambiguous provision. *United States ex rel. Donegan v. Anesthesia Assocs. Of Kansas City, P.C.*, 833 F.3d 874, 879 (8th Cir. 2016). For example, in *Donegan*, the matter turned on an anesthesiologist's duty vis-à-vis a patient's "emergence" from anesthesiology. *Id.* at 878. However, there was no regulatory definition of "emergence" or guidance as to how to interpret the term. *Id.* As a result, the Eighth Circuit found that it was objectively reasonable for the anesthesiologist to consider "emergence" as fulfilled when seeing a patient in a recovery, as opposed to operating, room. *Id.* at 879. In so finding, the court in *Donegan* observed that both the plaintiff and the defendant's experts agreed that "emergence" is a process with no defined end point and continues into a recovery room. *Id. Cf. Visiting Nurse Ass'n of Brooklyn v. Thompson*, 378 F. Supp. 2d 75, 95

[15] Defendant also argues that the nature of an SCS device justifies the conclusion that a separate physician order is not required. Def. MSJ. at 39-43. Among other things, Defendant points out that the SCS is considered a "permanent" device, that it is an option of "late" (if not last) resort, and that a physician order as to medical necessity is required before the SCS is first implanted. *Id.* The Court considers this argument to be one of "common sense" because BSNC does not cite any CMS (or other) authority to support its interpretation. While BSNC makes fair points, the Court can also reasonably foresee why CMS would not agree. For example, CMS could nevertheless be concerned about waste, fraud, and abuse in paying for replacement supplies. In any event, the Court finds that BSNC's argument does not carry the day due to its lack of authoritative support.

(E.D.N.Y. 2004) (rejecting the good faith misunderstanding defense because the providers did not show that they were confused by the relevant instruction or attempted to comply with them).

Nevertheless, there are limits to the defense of reasonable interpretation of an unclear directive. Some courts have found that the claimant must make some minimal, good faith effort to determine that its interpretation is correct. *See, e.g.*, *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (observing that as to the reckless disregard definition of knowing, a claimant has a limited duty to make a reasonable and prudent inquiry as dictated by the circumstances). Moreover, even when legal requirements are ambiguous, the timing of a defendant's reasonable interpretation is critical. *See United States ex rel. Phalp v. Lincare Holdings*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("Although ambiguity may be relevant to the scienter analysis . . . a court must determine whether the defendant actually knew or should have known that is conduct violated a regulation in light of any ambiguity *at the time of* the alleged violation." (emphasis added) (citation omitted)). In other words, a claimant cannot avoid liability by manufacturing an after-the-fact reasonable interpretation of an ambiguous provision. *Id.* In addition, an otherwise reasonable interpretation of ambiguous language will be no defense if the Government clarifies the meaning of the unclear provision before the claims are submitted. *Id.*; *see also Donegan*, 833 F.3d at 879 (observing that a defendant who had an otherwise objectively reasonable interpretation could still be liable under the FCA if Government guidance notified the defendant of the correct interpretation of the ambiguous language); *Visiting Nurse Ass'n*, 378 F. Supp. 2d at 96 ("[T]he safe harbor created for those who rely on a reasonable interpretation of an ambiguous provision" does not provide protection "where the agency responsible for administering the applicable law or regulation has publicly issued a definitive interpretation intended to resolve that ambiguity.").

1. The 2004 PIM Requirements

Before turning to a discussion of the PIM, a review of the changes to key terminology within the PIM is helpful. The relevant timeframe, 2006-2010, overlaps with a period of Medicare regulatory change. In 2005, the Department of Health and Human Services ("HHS") in its *Report to Congress Medicare Contracting Reforms: A Blueprint for a Better Medicare* ("Report") laid out Medicare's plan and timeline for improving Medicare's administrative services.[16] This plan included Medicare replacing its "current claims payment contractors – fiscal intermediaries (FIs) and carriers – with new contract entities, MACs [Medicare Administrative Contractors]" by October 2011. U.S. DEP'T OF HEALTH AND HUMAN SERV., REPORT TO CONGRESS: MEDICARE CONTRACTING REFORM: A BLUEPRINT FOR A BETTER MEDICARE (2005). For the most part, fiscal intermediaries serviced Medicare Part A claims while carriers handled Part B claims.[17]

The Report redesigned the oversight of receiving, processing, and paying Medicare claims submitted for reimbursement. *Id.* at III-2. The Report called for twenty-three MACs to take over the work of fiscal intermediaries and carriers. Fifteen of those MACs would be "A/B MACs servicing the majority of all types of providers, 4 [would be] specialty MACs servicing

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[16] The full report can be found at: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/2005-Report-To-Congress.pdf.

[17] As indicated, the major change concerned the discontinuance of fiscal intermediaries and carriers. In 2005, twenty-five fiscal intermediaries were tasked with processing claims for Medicare Part A, particularly for hospitals, skilled nursing facilities and, home health and hospice services. In addition, eighteen carriers were tasked with processing claims for Medicare Part B, particularly for physician, laboratory, and other services. Four of these carriers were tasked with serving as "durable medical equipment regional carriers (DMERCs) focusing exclusively on claims for durable medical equipment, prosthetics, orthotics, and supplies." U.S. DEP'T OF HEALTH AND HUMAN SERV., REPORT TO CONGRESS: MEDICARE CONTRACTING REFORM: A BLUEPRINT FOR A BETTER MEDICARE (2005).

the majority of home and health hospice (HH) providers, and 4 [would be] specialty MACs servicing durable medical equipment (DME) supplies." *Id.* Thus, the Report reflects the Department of HHS' intention to use, in lieu of fiscal intermediaries and carriers, three different types of MACs: A/B MACs, HH MACs, and DME MACs.

The Centers for Medicare and Medicaid Services ("CMS") began implementing the Report's planned changes in 2005. U.S. DEP'T OF HEALTH AND HUMAN SERV., REPORT TO CONGRESS: STATUS ON MEDICARE CONTRACTING REFORM IMPLEMENTATION (2011). For example, in 2006 CMS awarded and implemented three DME MAC contracts (58.4% of the DME MAC workload) and awarded and began implementation activities for one A/B MAC contract (2.7% of the A/B MAC workload). *Id.* at 5. The following year, CMS completed implementation for the first A/B MAC contract, awarded and implemented a fourth DME MAC contract, and awarded and began implementation activities for another two A/B MAC contracts. *Id.* In 2011, when the Department of HHS reported to Congress on CMS' progress in implementing the Report's plan to date, CMS had implemented all four of the DME MAC contracts and nine of the fifteen A/B MAC contracts. *Id.* at 1.

As noted, the supplies at issue were overseen by A/B MACs, not DME MACs. Moreover, the predecessor to DME MACs were carriers called Durable Medical Equipment Regional Carriers ("DMERCs"). The DMERC designation is critical to the Court's analysis because, as will be shown, the relevant Medicare guidance sometimes only referred to DMERCs, which means DME MACs rather than A/B MACs. The foregoing regulatory changes reflect that the PIMs did not keep pace with the reorganization and renaming by HHS. Indeed, to this day, the PIMs continue to refer to DMERCs as opposed to DME MACs.

This context, provides the backdrop to the central issue in this case, specifically whether the relevant Medicare guidelines required Defendant to obtain a written physician order before billing Medicare for replacement supplies associated with the SCS. Resolving the question requires examining the language in Chapter Five of the PIM.

The relevant sections of Chapter Five of the 2004 PIM contain language that arguably provide support for both parties' positions. On the one hand, Section 5.1.1 - Physician Orders of the PIM states that *all* DMEPOS require a physician order:

> The supplier for *all* Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) is required to keep on file a physician prescription order (order). The treating physician must sign and date the order. A supplier must have an order from the treating physician before dispensing any DMEPOS item to a beneficiary.

Def. MSJ.; DE. 299-18 (2004 PIM Ch. 5, § 5.1.1) (emphasis added). This section unmistakably applies to all supplier of DMEPOS, which would include Defendant, and requires a physician order.

The requirements for the physician orders are further explained in Section 5.1.1.2 - Written Orders:

> Written orders are acceptable for all transactions involving DMEPOS. Written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See Chapter 3, Section 3.4.1.1.B)
>
> All orders must clearly specify the start and date of the order.
>
> For items that are dispensed based on a verbal order, the supplier must obtain a written order that meets the requirements of this section.[18]

[18] Defendant points to the first paragraph of this section, specifically the "[w]ritten orders are acceptable" language, as proof that written orders are not necessary but only advisory. Def. Rep. at 6 n.3. However, this interpretation is not viable in light of language in the entire section, which clearly states that a supplier must get a written order if it originally relied on a verbal

> If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. (For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.)
>
> The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number.
>
> . . .
>
> If a supplier does not have a faxed, photocopied, electronic or pen & ink signed order in their records before they submit a claim to Medicare (i.e. there is no order or only a verbal order), the claim will be denied. If the item is one that requires a written order prior to delivery (see Section 5.1.1.2.1), the claim will be denied as not meeting the benefit category. If the claim is for an item for which an order is required by statute (e.g. therapeutic shoes for diabetic, oral anticancer drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see MCM Section 12000 for more information on appeals). For all other items, if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonably and necessary.
>
> . . .
>
> Medical necessity information (e.g., an ICD-9-Cm diagnosis code, narrative description of the patient's condition, abilities, limitations, etc.) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

Id. at § 5.2.2.

The section is not expressly limited to DME MACs or their predecessors. Thus, here too, CMS' chosen language appears to support Plaintiffs' position that the Government required all suppliers to have physician orders. Section 5.1.1 refers to *all* DMEPOS to keep physician orders

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order. In other words, a written order is always necessary, but a supplier can sometimes rely on a verbal order before obtaining the written form.

on file and Section 5.1.1.2 provides specific instructions for those orders, including that the orders must be in writing (even if initially communicated verbally).

Plaintiffs also point to 1999 guidance from HHS's Office of the Inspector General. Pl Opp. at 27. The guidance concerned appropriate compliance programs and stated in part:

> DMEPOS suppliers must keep the treating physician's or other authorized person's signed and dated order or CMN[, Certificate of Medical Need,] on file for all DMEPOS for all DMEPOS items and services The guidance continues: "Upon a payor's request, the DMEPOS supplier must be able to provide documentation, such as physician orders, . . . written confirmation of verbal orders and any other documentation to support the medical necessity of an item or service the DMEPOS supplier has provided and billed to a Federal . . . health care program.

U.S. DEP'T OF HEALTH AND HUMAN SERV., PUBLICATION OF OIG COMPLIANCE PROGRAM GUIDANCE FOR THE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLY INDUSTRY, 64 FED. REG. 36368-01, 3675 (1999).

The guidance, which predates the relevant claim submissions by over five years, does not distinguish between different DMEPOS suppliers. Moreover, Plaintiffs presented evidence that BSNC was actually aware of, and reviewed, the guidance. Pl. Opp. at 28. As a result, the guidance supports Plaintiffs' interpretation.

On the other hand, multiple sections of Chapter Five of the PIM arguably support Defendant's alternate position that the PIM did not clearly require a physician order for the claims at issue. Defendant primarily relies on Sections 5.1.1.1, 5.1.1.3, and 5.1.1.4.3. The cited sections do not refer to either A/B MACs or DME MACs. Instead, they refer to DMERCS and DMERC PSCs, which were the predecessors to DME MACs. Any reference to DMERC, therefore, can reasonably be read as limiting the requirements to DME MACs, which would exclude the MACs to whom Defendant submitted claims. Besides the sections relied on by Defendant, the Court notes that other sections of the 2004 PIM - such as 5.1.1.2.1 (addressing

"Written Orders Prior to Delivery"), 5.2.1 (concerning "Supplier Documentation"), and 5.3 (entitled "Evidence of Medical Necessity") – also explicitly refer to DMERCs and DMERC PSCs.

Section 5.1.1.1, entitled "Verbal Orders," indicates that other than as provided in Section 5.1.1.2.1, "suppliers may dispense most items or DMEPOS based on a verbal order." 2004 PIM Ch. 5, § 5.1.1.1. As relevant here, the section continues as follows: "Suppliers must maintain written documentation of the verbal order and this documentation must be available to the DMERC or *DMERC PSC*." *Id.* (emphasis in original). Section 5.1.1.1 concludes that a supplier cannot submit a claim to a DMERC or DMERC PSC without first having an order from the treating physician. *Id.*

Similarly, Section 5.1.1.3, "Requirement of New Orders," also only explicitly names DMERCs and DMERC PSCs:

> A new order is required in the following situation:
>
> - There is a change in the order for the accessory, supply, drug, etc.;
> - On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
> - When an item is replaced; and
> - When there is change in the supplier.
> - In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DMERC *or DMERC PSC.*

Id. at § 5.1.1.3 (emphasis in original).

Further, both the title and language of Section 5.1.1.4.3 only refer to DMERCs and DMERC PSC. The title is "DMERCs' *and DMERC PSCs'* Authority to Assess an

Overpayment and/or CMP When Invalid CMNs Are Identified." In relevant part, the section provides:

> Section 1862(a)(1)(A) of the Act prohibits Medicare payment for services that are not reasonable and necessary. Section 1833(e) of the Act requires that Medicare be furnished by providers and suppliers "such information as may be necessary in order to determine the amount due. . . ." These sections provide support that a failure to have a valid CMN on file or to submit a valid CMN to the DMERC *or DMERC PSC* makes the underlying claim improper because Medicare does not have sufficient information to determine whether the claim is reasonable and necessary. A valid CMN is one in which the treating physician has attested to and signed supporting the medical need for the item, and the appropriate individuals have completed the medical portion of the CMS. When the DMERCs *and DMERC PSCs* identify a claim for which a CMN is not valid, they may deny the claim and/or initiate overpayment action.
>
> If a DMERC *or DMERC PSC* identifies a supplier that has a pattern of improperly completing the CMN the DMERC *or DMERC PSC* may choose to develop a potential Civil Monetary Penalty (CMP) against the supplier.

Id. at § 5.1.1.4.3 (emphasis in original).

Given the foregoing language in Chapter Five of the 2004 PIM, the Court finds that there are sections that can reasonably be read as requiring a detailed physician order for all suppliers of DMEPOS, including Defendant. Yet, given numerous explicit references to DMERCs and DMERC PSC, the Court also notes that Defendant's point as to ambiguity is well taken.[19] Thus, the Court finds that Chapter 5 of the 2004 PIM can reasonably be construed as ambiguous.

[19] One reason for the ambiguity could be changes that Medicare was going through at the time, specifically transitioning from fiscal intermediaries and carriers to A/B MACs and DME MACs. Perhaps, the nomenclature in the regulatory guidance was not amended until the transition was definite and complete. For example, the 2016 MCPM, Section 10.2, expressly indicates that it applies to both A/B and DME MACs, states that a physician prescription is required, and references Chapter Five of the PIM.

2. Defendant's Knowledge

Since Chapter Five of the 2004 PIM is arguably ambiguous, the Court must next analyze whether BSNC acted in good faith and with a reasonable interpretation that Chapter Five did not require it to obtain physician orders. As noted, this inquiry focuses on Defendant's knowledge *at the time* it submitted the claims. It does not apply to an otherwise reasonable interpretation that was created after-the-fact.

Defendant has pointed to no evidence to support its contention that it was acting pursuant to a reasonable interpretation of Chapter Five during the relevant timeframe, Def. MSJ. at 43-44, with the exception of a letter it claims to have submitted to Palmetto, the A/B MAC. That letter is discussed in the next section. For example, Defendant points to no evidence that it sought outside guidance or legal advice as to the reasonableness of its interpretation during the time that it was actually submitting the claims. *Cf. Williams*, 696 F.3d at 531 (finding that the defendant did not knowingly submit false claims because, among other things, the defendant "sought legal counsel on the issue" and the "defendant's legal counsel sought clarification on the rules from CMS officials").

Moreover, Plaintiffs have also pointed to sufficient evidence to create a genuine issue of material fact as to Defendant's knowledge, that is, BSNC believed that it was subject to the detailed physician order requirement when it submitted the relevant claims. Plaintiffs, for example, cite evidence reflecting that BSNC knew that it needed a written physician order on file before placing orders. *See* 30(B)(6) Deposition of Boston Scientific (Wendy Chan) 94:6-95:19; D.E. 353-14, Exhb. 29; Deposition of Dawn Le Manna 41:5-8; D.E. 358-2, Exhb. 47. In fact, Plaintiffs evidence extends beyond the time when Defendant was actually submitting claims to the earlier stages of this litigation. First, Defendant answered Plaintiffs' interrogatory question

of "[i]s it your contention that physicians orders were *not* required before you submitted claims for external accessories to the Precision Plus SCS System?" with a perfunctory "[n]o." Pl. Opp.; D.E. 313-3 (Defendant's Supplement and Amended Answers to Relators First Set of Interrogatories ¶22 (emphasis added)). Second, Defendant's 30(b)(6) witness, Wendy Chan, made several statements suggesting that BSNC believed it needed to include a physician order with claims for SCS supplies. The following is an example:

> Q. Just so there isn't any doubt at trial, Boston Scientific understands that if it does not have a signed physician order for a particular SCS supply claim in Boston Scientific's files before submitting the claim to Medicare, Medicare will deny that claim, isn't that true?
>
> Ms. Reynolds: Objection. Form.
>
> The Witness: That's what it states here.
>
> Q. That's what it states here in the Medicare rules; correct?
>
> A. Yes.

Pl. Opp.; D.E. 313-29 (30(B)(6) Deposition of Boston Scientific 96:18-97:4). The foregoing evidence is sufficient to defeat BSNC's motion for summary judgment as to its knowledge of the physician order requirement.

In light of the foregoing, the Court finds that there is a genuine issue of material facts as to BSNC's knowledge that precludes summary judgment.

B. Palmetto Letter

Defendant also argues that it is entitled to summary judgment because BSNC informed the Government of its allegedly fraudulent billing practices. Def. MSJ. At 52. Defendant points to BSNC's alleged sending of a December 7, 2009 letter to Palmetto GBA, the A/B MAC responsible for processing the Medicare claims for replacement supplies. DSOMF ¶ 42; Def.

MSJ., D.E. 299-16 ("Palmetto letter"). BSNC claims that in the Palmetto letter, it "disclosed BSNC's billing process for 'claims for Medicare reimbursement for certain of its external ancillary replacement products' and sought 'confirmation' that Palmetto agreed with those practices." Def. MSJ. at 54. Further, Defendant claims not only that it made the Government aware of its billing practices, but also that the Government condoned those practices through its continuing payment of BSNC's claims. To strengthen its position, Defendant cites to the following passage from *Escobar*:

> [I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

136 S. Ct. at 2003–04.

The Court disagrees with Defendant's claim of entitlement to summary judgment based on the Palmetto letter. Legally, the language from *Escobar* indicates that informing the Government of the relevant conduct is "strong," not conclusive, evidence of immateriality.[20] Factually, Plaintiffs have raised genuine and material issues as to whether Palmetto ever received the letter. Pl. Opp. at 49. Plaintiffs point out that BSNC's corporate witness was unable to

[20] BSNC also points to several circuit decisions in support of its arguments. Def. MSJ. at 53-54. For instance, Defendant refers to the following language from *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 496 (D.C. Cir. 2004): "[I]f the claimant told the [government official] pertinent facts that would, in the absence of such disclosure, make a claim fraudulent, it seems that the claimant has not 'knowingly' presented a false claim[.]" Of course, *Escobar* is a Supreme Court decision, which is binding on all circuit courts. While the Court recognizes the language in *Escobar* is dicta rather than a holding, it does provide strong evidence of the manner in which the Supreme Court views the issue. Moreover, even were the Court to find that full disclosure of all pertinent information to the Government precludes a finding of knowing conduct as a matter of law, there are nevertheless factual issues as to whether BSNC made the required complete disclosure and whether Palmetto received the letter.

definitively testify about BSNC sending the Palmetto letter. *Id.* Further, Defendant did not produce mailing or receipt records of the Palmetto letter. *Id.* It goes without saying that a defense of full disclosure to the Government depends, as a threshold matter, on the Government actually receiving the disclosure. Plaintiffs also point to genuine issues of material fact regarding whether Defendant fully disclosed the necessary information about BSNC's billing practices in the Palmetto letter. Pl. Opp. at 53. Plaintiffs assert that the Palmetto letter did not disclose, among other things, BSNC's lack of physician orders for submitted claims or that BSNC's billing department changed billing codes and altered physician orders after the physician had signed the order. *Id.* In the Palmetto Letter, BSNC did indicate when billing for replacement supplies, "it is not always viable to communicate with the treating physician regarding the patient's diagnostic code in a timeframe that meets the patient's need." The letter continues that in such situations, BSNC includes one of two diagnostic codes because Palmetto will reject the claim without a diagnostic code. The Court agrees with Plaintiffs. A fair reading of the Palmetto letter could[21] lead a jury to reasonably conclude that Defendant failed to disclose all material facts to Palmetto. Therefore, the Court denies summary judgment based on the Palmetto letter.

C. Incorrect Diagnosis Codes

Defendant, additionally, argues that the Court should grant it summary judgment because BSNC did not submit 564 claims with false diagnosis codes. In the alternative, Defendant claims if BSNC did submit claims with false diagnosis codes, then it would still not be liable under the FCA because diagnosis codes are not material to the Government's decision to pay the

[21] The Court's finding as to the completeness of the disclosure in the Palmetto letter is only for purposes of summary judgment. The Court is not ruling that the letter will necessarily be inadmissible at trial.

claims at issue. Def. MSJ. at 50-51. Specifically, Defendant asserts that the Government does not require SCS system external accessories to be billed with a specific diagnosis code. Therefore, Defendant concludes that the diagnosis codes BSNC's billing department used would not impact whether or not the Government reimbursed the claims. *Id.* at 52.

The Court again finds that summary judgment is inappropriate here because multiple material issues of fact remain in dispute. Diagnosis codes are part of the documentation that makes a medical record and claims related to treatment complete. In fact, in the Palmetto letter, Defendant acknowledged that Palmetto would not process the submitted claims without diagnosis codes. In short, Defendant's argument is that the codes were necessary for the claims to be processed but immaterial to the actual payment decision. Defendant claims that such claims are not "literally" false. Def. MSJ. at 51. This argument is puzzling. It seems that submitting diagnosis codes that were inserted by BSNC, without either a physician order or different from the code submitted by the physician, would clearly meet the definition of being literally false. As Plaintiffs point out, the evidence supports finding that BSNC directly misled Medicare. BSNC "falsely reported that a medical provider had issued the diagnosis code specified on the claims they submitted to Medicare." Pl. Opp. at 46. Further, "[t]he record is clear that BSNC had *no* diagnosis code from the physician for these claims, or a diagnosis code that in fact was *different from* the one it reported to Medicare." *Id.* (emphasis in original).[22] Thus, Plaintiffs argue BSNC knowingly submitted false claims. *Id.*

[22] In their Amended Complaint Plaintiffs include four tables that they allege evidence BSNC's knowingly false submission of fabricated diagnosis codes to Medicare. *See* Am. Compl. ¶¶ 37–41.

Instead, the Court views Defendant's argument as turning on materiality. To this end, Defendant has not cited any authority to support its argument that the allegedly fabricated diagnosis codes were immaterial as a matter of law.[23] At this stage, the Court agrees with Plaintiffs that material issues of fact remain in dispute. Defendant has not illustrated that the Government would find it immaterial as a matter of law that BSNC knowingly submitted claims with diagnosis codes that differed from the physician's diagnosis code or which it inserted without physician input. As noted, Defendant has not provided, and the Court has not found, that in an applicable situation a court found similar falsity immaterial. Thus, summary judgment is not appropriate.

D. Identifying Claims & Claim Lines

Defendant next argues that BSNC is entitled to summary judgment because Plaintiff allegedly inflated claim lines and because Plaintiffs will not be able to show which claims BSNC submitted are allegedly false. Def. MSJ. at 56,70. The Court finds it inappropriate to address these arguments here at the summary judgment stage. Both arguments present issues better addressed through motions *in limine* concerning the evidence that Plaintiffs will be able to present and how the jury will be instructed. Thus, the Court will not reach these issues at this juncture.

E. The Constitutionality of FCA Penalties

Finally, Defendant argues that Plaintiffs' alleged penalties are unconstitutionally excessive. Def. MSJ. at 65. Plaintiffs disagree and assert that they are only seeking treble

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[23] BSNC also claims that Plaintiffs' expert admitted that the codes were immaterial. Def. MSJ. at 52. Plaintiffs point to contrary evidence demonstrating that the expert's testimony was actually concerning an edit function in the A/B MACs system. Pl. Opp. at 48 n.15. Suffice it to say, the expert's testimony on the point presents a factual issue not appropriate for resolution on summary judgment.

damages and a civil penalty within the statutory range that 31 U.S.C. § 3729 authorizes. Pl. Opp. at 60. Defendant counters that the "FCA's statutory penalties and trebling of damages are, at least in part, punitive and subject to the Eight Amendment's Excessive Fine Clause and the Fifth Amendment's Due Process Clause." Def. Rep. at 21.

First, insofar as Defendant is challenging the constitutionality of 31 U.S.C. § 3729 on its face, the Court disagrees. The FCA has been in existence since the Civil War, and no court (much less the United States Supreme Court) has found its penalty provisions to be facially unconstitutional. In *Escobar*, the Court plainly acknowledged that the FCA "imposes significant penalties on those who defraud the Government." 136 S. Ct. at 1995. The Supreme Court continued that FCA defendants "are subjected to treble damages plus civil penalties of up to $10,000 per false claim[.]". *Id.* at 1996. Second, insofar as Defendant is challenging the constitutionality of the statute as applied to the facts in this case, the Court finds Defendant's argument premature. At this stage, it is not clear yet what, if any, liability Defendant will have. Therefore, the Court will rule on this argument at the appropriate juncture if necessary.

IV. CONLCUSION

For the reasons stated above, Defendant's motion for summary judgment (D.E. 299) is **DENIED**. An appropriate Order accompanies this Opinion.

Dated: December 15, 2017

John Michael Vazquez, U.S.D.J.